Amukin 50% - Airspray(R)
Dated: November 29, 1988
706 Received: December 5, 1988
15 Regulatory Class: II

on 510(k) notification of intent to market the device
e determined the device is substantially equivalent
rstate commerce prior to May 28, 1976, the enactment
Amendments. You may, therefore, market the device,
rols provisions of the Federal Food, Drug, and
neral controls provisions of the act include
istration, listing of devices, good manufacturing
d prohibitions against misbranding and adulteration.

d (see above) into either class II (Performance
emarket Approval) it may be subject to such
ng major regulations affecting your device can be
Regulations, Title 21, Parts 800 to 895. In
Administration (FDA) may publish further
r device in the Federal Register. Please note:
ket notification submission does not affect any
der the Radiation Control for Health and Safety Act
ent to submit an initial report prior to marketing
or other applicable Federal laws or regulations.

allow you to begin marketing your device if you
nts described above. An FDA finding of substantial
o a pre-Amendment device results in a classification
your device to proceed to the market, but it does
our device. Therefore, you may not promote or in
e or its labeling as being approved by FDA. If you
e labeling for your device, please contact the
tions, Regulatory Guidance Branch (HFZ-323) at
al information on your responsibilities under the
e Division of Small Manufacturers Assistance at
638-2041 or at (301) 443-6597.

Sincerely yours,

Halyna P. Breslawec, Ph.D.
Director
Division of Gastroenterology-Urology
and General Use Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

nation is herein being submitted in conformance with 21 CFR

n Name: None
ual Name: Disinfectant for connector sites used in dialysis
etary Name: Amuchina 50% Airspray•

nt Registration Number: The establishment registration number
a Soc.p.Az. is 8021034.

n: Amuchina 50% Airspray• has not been classified by the
chemical composition of Amuchina 50% Airspray• is being
s Exhibit A.

Standards: No performance standards applicable to the
of connector sites used in dialysis have been established by

is enclosed as Exhibit B.

hina 50% Airspray on connector sites in dialysis is substantially
using povidone iodine on connector sites. The equivalency
50% Airspray on connector sites in dialysis is supported by
:

etermination of the Sporicidal Effectiveness of Two Sporicidal

ffectiveness of AMUKIN-50% in a "Y"-Set for CAPD Treatment
ments No. 1-11);

afety of AMUKIN-50% in a "Y"-Set for CAPD Treatment (with
No. 12).

otification

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Set, Administration, For Peritoneal Dialysis, Disposable
K871583
MODIFIED LABELING FOR AMUKIN-50%
AMUCHINA INTL., INC.
12120a Heritage Park Circle
Silver Spring, MD 20906
Cooney, Pa
876.5630
e KDJ
04/23/1987
07/09/1987
Substantially Equivalent (SE)
mmittee Gastroenterology/Urology
e Gastroenterology/Urology
Traditional
No

lotification

Back To Search Results

Name	System, Peritoneal, Automatic Delivery
	K862928
	AMUKIN-50% FOR CAPD Y-SET
	AMUCHINA INTL., INC. 12120a Heritage Park Circle Silver Spring, MD 20906
	Bernard J Cooney
	876.5630
ct Code	FKX
	08/01/1986
	03/09/1987
	Substantially Equivalent (SE)
ory Committee	Gastroenterology/Urology
mmittee	Gastroenterology/Urology
	Traditional
arty	No